JAN 26 2006

K051447

510(k) Summary

Submitter's Name/Address
Sentinel CH. Srl
Via Principe Eugenio 5
20155 Milan - ITALY

Contact Person
Mr. Davide Spada
Application Specialist
Telephone: +39 02 345514.1
Facsimile: +39 02 345514.64
E-Mail: spada@sentinel.it

Date of Preparation of this Summary: January 19, 2006

Device Trade or Proprietary Name: Sentinel Pancreatic Amylase

Device Common/Usual Name or Classification Name: Pancreatic Amylase

Classification Number/Class: JFJ/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Test Description:

The Sentinel Pancreatic Amylase is an in vitro diagnostic assay for the quantitative determination of pancreatic amylase in serum or plasma. The Sentinel Pancreatic Amylase is a two-reagent format that is carried out in two successive steps. In the first incubation step, the activity of the human salivary alpha-amylase is inhibited using two different monoclonal antibodies with no effect on the pancreatic alpha-amylase. In the second reaction step, the pancreatic alpha-amylase catalyses the hydrolysis of the EPS substrate (Ethylidene Protected Substrate) p-nitrophenyl-maltoheptaoside 4,6-ethylidene-blocked (Ethylidene-G7PNP) forming 2 ethylidene-G4 + 2 G3PNP + ethylidene-G3 + G4PNP. The α-glycosidase hydrolyses all fragments of G2PNP, G3PNP, and G4PNP into p-nitro phenol (PNP) and glucose (G). The increase of

absorbance, due to PNP formation, is proportional to the activity of pancreatic alpha-amylase in the examined sample.

Substantial Equivalence:

The Sentinel Pancreatic Amylase is substantially equivalent to the Roche Pancreatic Amylase assay (K895880) on the Roche analyzer. These assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro clinical chemistry methods.
- Both assays can be used for the quantitative determination of pancreatic amylase.
- Both assays yield similar clinical results.

Differences:

There is a difference between the assay ranges.

Intended Use:

The Sentinel Pancreatic Amylase is used for the quantitation of pancreatic amylase in serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® and ARCHITECT® *c*8000® analyzers.

Method comparison studies of the Pancreatic Amylase on the AEROSET analyzer yielded acceptable correlation with the Roche Pancreatic Amylase assay on the Hitachi 911 Analyzer. The correlation coefficient = 0.9994, slope = 0.965, and Y-intercept = 3.843. Samples ranged from 5 to 2428 U/L.

Method comparison studies of the Sentinel Pancreatic Amylase on the ARCHITECT *c*8000 analyzer yielded acceptable correlation with the Sentinel Pancreatic Amylase on

the AEROSET analyzer. The correlation coefficient = 0.9998, slope = 1.011, and Y-intercept = -0.796. Samples ranged from 4 to 2290 U/L.

Precision studies were conducted using the Sentinel Pancreatic Amylase. Within-run, between-run, and between-day studies were performed on the AEROSET analyzer using three levels of control material. The total %CV for Level 1 is 3.99%, Level 2 is 1.64%, and Level 3 is 1.11%. Within-run, between-run, and between-day studies were performed on the ARCHITECT *c*8000 analyzer using two levels of control material. The total %CV for Level 1 is 1.50% and Level 2 is 0.60%.

The Sentinel Pancreatic Amylase is linear up to 2200 U/L. The limit of detection (sensitivity) of the Sentinel Pancreatic Amylase is 1 U/L.

These data demonstrate that the performance of the Sentinel Pancreatic Amylase is substantially equivalent to the performance of the Roche Pancreatic Amylase assay on the Hitachi 911 analyzer.

Conclusion:

The Sentinel Pancreatic Amylase is substantially equivalent to the Roche Pancreatic Amylase assay on the Roche analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 2006

Mr. Davide Spada
Application Specialist
Sentinel CH. S.r.l.
Via Principe Eugenio, 5
20155 Milan- Italy

Re: k051447
Trade/Device Name: Sentinel Pancreatic Amylase
Regulation Number: 21 CFR§862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ
Dated: January 3, 2006
Received: January 12, 2006

Dear: Mr. Spada

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051447

Device Name: Sentinel Pancreatic Amylase

Indications For Use:

The Sentinel Pancreatic Amylase is used for the quantitation of pancreatic amylase levels in human serum or plasma. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). For *In Vitro* use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K051447